



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,162	08/26/2003	Raymond E. Ideker	5656-33	3541

7590 02/27/2007
Laura M. Kelley
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, NC 27627

EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
----------	--------------

3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/648,162

Applicant(s)

IDEKER, RAYMOND E.

Examiner

Eric D. Bertram

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-18, 21-49 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-18, 21-49 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2006 has been entered.

Response to Arguments

1. Applicant's arguments filed 12/18/2006 have been fully considered but they are not persuasive. The applicant initially argues that "there is no motivation to chronically detect electrical activity in the heart using internally implanted electrodes" as recited in claims 1, 18 and 38. First off, as described in the previous Office Action, upon reviewing the specification, the applicant merely describes chronic detection as detection "over an extended duration of time," and that the detection need not be continuous (page 3, lines 30-35). Therefore, since "chronically" is a relative term, and no actual time scales are supplied by the applicant to appropriately define the term, any detection that occurs more than once shall be considered "chronic detection."

2. Furthermore, as noted by the applicant, Korta discloses 60 electrodes are attached to the epicardium of the heart of the patient. As is well known in the art, the heart is an internal organ. Therefore, despite the fact that the pericardium is exposed, any electrodes implanted on the heart are inherently internally implanted. For example,

Art Unit: 3766

if items were placed inside of a paper shopping bag, they would not be considered outside of the bag even though the top of the bag may be open. In much the same way, even though the pericardium is exposed, it is still the inside of the body, and, accordingly, the electrodes are internally implanted. Therefore, the 35 USC 103(a) rejection of claims 1-3, 5, 7, 8, 12-21, 25, 26, 28, 30, 31, 33-40, 42, 44, 45, and 49-54 is still considered proper.

3. Regarding claims 6, 29 and 43, as described in the previous actions and below, Konta discusses that discordant alternans are related to the development of ventricular fibrillation, which is a life-threatening condition requiring immediate treatment in a patient (page 2187, Col. 1). Furthermore, Konta does state that discordant alternans can be suppressed by treatment with the drug verapamil (page 2188, Col. 1).

Therefore, Konta suggests delivery of the drug verapamil to a patient following the detection of discordant alternans in order to prevent or treat the occurrence of ventricular fibrillation, as is suggested by Konta. Since this would include any detection of discordant alternans, it would inherently include the detection of discordant alternans from concordant alternans. Therefore, the 35 USC 103(a) rejection of claims 6, 29 and 43 are still considered proper.

4. Regarding claims 9, 32 and 46, Konta discloses that the drug verapamil helps to prevent the development of ventricular fibrillation, as described above. Furthermore, it is well known in the art that verapamil is a calcium channel blocker that works to slow the generation of impulses in the heart. Therefore, since the atria will be affected by this as well, verapamil will inherently help reduce the risk of atrial fibrillation from

Art Unit: 3766

occurring since the atria will be unable to beat rapidly due to the blocking of the calcium channels. Therefore, the 35 USC 103(a) rejection of claims 9, 32 and 46 are still considered proper.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 5-9, 12, 15-18, 21, 25, 26, 28-40, 42-46, 49 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta et al. (*Significance of Discordant ST Alternans in Ventricular Fibrillation*, hereinafter Konta). Konta discloses a method and system for detecting discordant alternans in a subject wherein 60 silver electrodes are attached at distinct locations on the exposed pericardium of a patient in order to allow for the chronic detection of electrograms over a 7 minute occlusion period using a data processing system (page 2185, Col. 2). In order to identify the discordant alternans, the voltages of the ST segments from adjacent leads were compared to

Art Unit: 3766

determine of the alternans where in phase (concordant) or out of phase (discordant) (page 2186, Col. 1, par. 2). However, Konta does not specifically disclose initiating interventional therapy in response to the identification of discordant alternans.

Regardless, Konta discusses that discordant alternans are related to the development of ventricular fibrillation, which is a life-threatening condition requiring immediate treatment in a patient (page 2187, Col. 1). Furthermore, Konta does state that discordant alternans can be suppressed by treatment with the drug verapamil (page 2188, Col. 1). Therefore, despite the fact that Konta does not distinctly teach initiating therapy following detection of discordant alternans, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to deliver the drug verapamil to a patient following detection of discordant alternans in order to prevent or treat the occurrence of ventricular fibrillation, as is suggested by Konta.

8. Regarding claim 33, Konta further discloses an external electrode for recording surface electrograms, demonstrating that the use of external electrodes to monitor cardiac electrograms is notoriously old and well known in the art.

9. Claims 4, 27 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta in view of Pastore et al. (US 6,965,797, hereinafter Pastore). Konta, as described above, discloses the applicant's basic invention with the exception of using alternations in an activation recovery interval (ARI) to identify discordant alternans. Attention is directed to the secondary reference of Pastore, which teaches that the activation recovery interval of heart tissue may be used to identify pulse alternans, of which discordant alternans may be included. Therefore, it would have been obvious to

Art Unit: 3766

one of ordinary skill in the art at the time of the applicant's invention to modify the method and system of Konta by using ARI to identify discordant alternans since this is a known method of determining the existence of alternans in the heart.

10. Claims 10, 11, 22-24, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta in view of Christini et al. (US 6,915,156, hereinafter Christini). Konta, as described above, discloses the applicant's basic invention with the exception of applying electrical stimuli to the heart in order to provide therapy to a patient in response to the detection of discordant alternans. Attention is directed to the secondary reference of Christini, which discloses applying electrical stimuli to a patient in order to control and stabilize discordant alternans in a patient (Col. 6, lines 53-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system/method of Konta by applying electrical stimuli to a patient since this is a known technique for stabilizing discordant alternans, as taught by Christini.

Conclusion

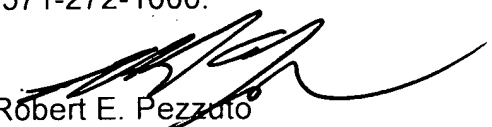
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB